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Role of Intravascular Ultrasound use in Patients Undergoing Endovascular Aorto-iliac Aneurysm Repair

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ORIGINAL ARTICLE

Role of Intravascular Ultrasound Use in Patients Undergoing Endovascular Aorto-iliac Aneurysm Repair

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Abstract

Background: **Early endovascular procedures were used to treat elderly patients with severe coexisting conditions who could not undergo open surgery.**

Aim: **The study aimed to evaluate the intravascular ultrasound (IVUS) effectiveness in performing endovascular repair of abdominal aortic aneurysm (EVAR) and its involvement in chronic renal disease, as well as to compare the accuracy of aortic measurements performed with IVUS and intra-arterial contrast agent.**

Patients and methods: **Between December 2017 and December 2019, this prospective, randomized, single-blinded research was carried out at military hospitals and Al-Azhar University hospitals. It included 20 patients complaining of infrarenal abdominal aortic aneurysm. According to treatment policy, patients were randomly split into two groups: group A: managed by EVAR with an intra-arterial contrast agent. Group B: treated by EVAR with IVUS.**

Results: **Based on receiver operating characteristic curve analysis, access artery diameter (right or left iliac) by IVUS can significantly predict the effect of EVAR in decreasing aneurysmal size (area under the curve = 0.88, $P = 0.003$). At cut-off more than 14 mm, access artery diameter gives a sensitivity of 100 %, specificity of 80 %, positive predictive value of 83.3 %, and negative predictive value of 100 %. There was a reasonable agreement between CT and IVUS in evaluating different aortic measurements.**

Conclusion: **Based on our analysis, we concluded that IVUS is a valuable tool in assessing the aortic measures accurately when compared to computed tomography; therefore, in the repair of abdominal aortic aneurysm.**

Keywords: Chronic kidney disease, Computed tomography angiography, Endovascular aorto-iliac aneurysm repair, Intravascular ultrasound

1. Introduction

Since Juan Parodi's groundbreaking 1991 publication, endovascular repair of aortic aneurysms (EVAR) has become a standard procedure around the globe. Since this original announcement, a number of inventors have attempted to increase the scope of EVAR's therapeutic applications in the care of patients with complicated anatomy.[1,2]

Early endovascular procedures were utilized to treat elderly individuals with severe comorbid conditions who could not undergo open surgery. The indications for this less intrusive approach have increased significantly since it was initially used, nevertheless. Currently, EVAR is used more often than surgical repair to treat patients with anatomically appropriate infrarenal abdominal aortic aneurysms (AAA).[3,4]

EVAR patients' perioperative survival rates have continuously increased because of advancements in endovascular procedures. Intra-arterial contrast agents (IACA) are necessary for EVAR operations because they help to confirm the aortic aneurysm morphology and locate the renal and hypogastric ostia. IACA is not advised for usage in individuals with renal disorders or contrast agent allergies. IACA has been replaced by intravascular ultrasonography (IVUS) since the 1990s.[5–7]

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When performing aortic procedures, IVUS offers real-time imaging, which is essential for diagnosing and treating aortic diseases such aneurysms, dissections, and penetrating aortic ulcers. The use of IVUS enables the anatomical definition of the target vessels and the linkage of branch vessels to the lesion, both of which are essential for effective endovascular therapy, endograft selection, and diagnostics.[8−11]

During endovascular abdominal aortic aneurysm repair (EVAR), IVUS is useful for assessing access vessels, proximal and distal fixation locations, and appropriate vessel size for endograft selection. The renal arteries for EVAR, among other significant anatomical features, may be discovered and identified. Then, IVUS may provide imaging data that angiography alone could not give, hence lowering the radiation dosage and contrast burden, which is crucial for patients with impaired renal function.[12]

The aim of this study is to evaluate the IVUS's effectiveness in performing EVAR and its involvement in chronic renal disease, as well as to compare the accuracy of aortic measurements performed with IVUS and IACA.

2. Patients and methods

It was approved by faculty council and university council. This randomized prospective single-blinded trial was carried out at Al-Azhar University hospitals and military armed forces hospitals from December 2017 to December 2019. It included 20 patients complaining of infrarenal AAA. According to treatment policy, patients were randomly split into two groups: group A: consisted of 10 patients with infrarenal AAA whom EVAR treated with an IACA. Group B: consisted of 10 patients with infrarenal AAA whom EVAR treated with IVUS.

2.1. Inclusion criteria

Nonruptured AAA with a diameter more than 5.5 cm or more than 0.5 mm increase in diameter in the past 6 months, aortic neck length more than 15 mm, aortic neck diameter less than 28 mm, the aortic neck should be free of thrombus and calcification, aortic neck angulation less than 60°, aortic bifurcation diameter more than 18 mm, access artery diameter (iliac) more than 7 mm, renal malfunction (serum creatinine level >1.4 mg/dl) for IVUS use, allergy to contrast for IVUS use and signed informed consent.

2.2. Exclusion criteria

Aortic neck diameter more than 28 mm, aortic neck length less than 15 mm, aortic neck angulation more than 60°, severe iliac tortuosity, extensive aortic neck thrombus, access artery diameter (iliac) less than 7 mm, aortic bifurcation diameter less than 18 mm, bilateral common iliac aneurysm requiring coverage of both hypogastric arteries, and superior mesenteric artery occlusions, essential accessory renal artery.

2.3. Patient selection considerations

Patients chosen for EVAR with IACA or IVUS should meet the necessary clinical and morphologic requirements. Written medical histories that include the patient's medical and surgical histories, a list of their current medicines, their history of allergies, and their vascular risk factors should all be included in the documentation. Physical examination includes palpation (pulsatile abdominal mass), auscultation (bruit over abdominal mass), a detailed vascular examination: pulse volume recordings, skin lesions, ankle−brachial indices, and a thorough general examination are all necessary to rule out serious concomitant disorders.

2.4. Investigations

Laboratory (platelet count, blood sugar level, kidney, liver, and coagulation profile), radiological: one or more of the following imaging investigations: computed tomography angiography (CTA) is a primary choice, magnetic resonant angiography, if the patient has contraindications to the above duplex ultrasonographic (US) examination.

2.5. Procedure

According to the aforementioned criteria, each patient was examined individually and then sent to EVAR utilizing either an IACA or an IVUS. The surgery was carried out in the operating room using a radiologic angiography suite using a fully aseptic method. Each procedure's specifics were separately recorded after completion, including: anesthesia: local, regional, or general, arterial access (open femoral artery exposure or percutaneous access), use of IACA or IVUS, duration of the procedure, equipment used: sheath (Fr) size, guidewire type, guiding catheters used, type of endograft delivered, size of contralateral limb placed, proximal and distal fixation points as well as all overlap points should then be angioplastied (ballooned), detection of the presence of endoleaks (angiogram or IVUS).

2.6. Medications

2.6.1. Periprocedural

Cessation of chronic anticoagulation is necessary before EVAR, but antiplatelet agents can be continued unless epidural anesthesia is planned. Patients with marginal renal function may be prehydrated, and sodium bicarbonate, N-acetylcysteine, and isosmolar contrast agents may be considered. Perioperative antibiotics and subcutaneous heparin are administered.

2.6.2. Intraprocedural

Patients will receive a bonus of 5000 IU of heparin (70–100 U/kg) after insertion of the sheath in the common femoral artery. Postprocedural: clopidogrel 75 mg/day for 12 weeks, aspirin 100 mg/day, and statins (atorvastatin) 20 mg/day for 90 days.

2.6.3. Study endpoint

Technical success is defined as the ability to successfully perform EVAR by either IACA or IVUS and immediate morphological success. Technical success without any significant adverse cardiac and cerebrovascular events occurring while the patient is hospitalized is known as procedural success. The relief of symptoms and signs of abdominal mass defines clinical success. Periprocedural complications and 30 days mortality all were recorded and dealt with individually.

2.6.4. Patient follow-up

At 1, 3, 6, and 12 months after the treatment, patients had follow-up clinic visits to assess their progress. Regarding the following points: sustained clinical improvement (absence of abdominal, urinary symptoms, and pulsating mass), monitoring of kidney function, the control of risk factors (e.g. smoking, diabetes mellitus, hypertension, hyperlipidemia), and color duplex ultrasound and CTA scan. It is possible to identify endoleaks, aneurysm sac enlargement, stent fracture, limb kinking, and material fatigue by postoperative monitoring.

2.7. Statistical analysis

Was carried out utilizing IBM Co. SPSS, version 28 (IBM, Armonk, New York, USA). When applicable, qualitative variables were examined utilizing the χ^2 test or Fisher's exact test and provided as frequency and percentage (%). By analyzing the receiver operating characteristic (ROC) curve, the overall diagnostic effectiveness of aortic measures was evaluated. The total test performance is assessed utilizing the area under the curve (AUC), with an AUC of roughly 100 % being the best test performance and one of more than 50 % denoting satisfactory performance. Statistical significance was defined as a two-tailed P value less than 0.05. The Bland–Altman analysis evaluated how well CT and IVUS agreed on the various aortic parameters.

3. Results

This prospective research was conducted at Al-Azhar University hospitals and military armed forces hospitals from December 2017 to December 2019 on 20 patients complaining of infrarenal AAA, split into two groups: group A: included 10 patients with infrarenal AAA whom EVAR treated with an IACA, and group B: included 10 patients with infrarenal AAA who were treated by EVAR with IVUS.

Table 1 shows that the two studied groups were comparable in age and sex distribution (Fig. 1).

Regarding the prevalence of diabetes mellitus, hypertension, cardiac ailment, and smoking, there was no statistically substantial variation between the two groups (Fig. 2).

Regarding the complaint, there was no statistically substantial variation between the two groups.

Table 2 shows that by comparing both groups regarding aortic measurements, access artery diameter (right or left iliac) was substantially greater in group B (treated by EVAR with IVUS) as compared to group A (treated by EVAR with IACA) ($P = 0.003$). However, there was no statistically substantial variation between the two groups for AAA diameter, aortic bifurcation diameter, aortic neck angulation, aortic neck diameter, or aortic neck length (Fig. 3).

Serum creatinine level was substantially different between the studied groups being higher in patients treated by EVAR with IVUS as compared with those treated by EVAR with IACA ($P < 0.001$).

Table 3 showed that all the studied patients had general anesthesia and underwent arterial cutdown for arterial access. Patients treated by EVAR with IVUS had significantly longer procedural duration as compared with those treated by EVAR with IACA

Table 1. Demographic information for the examined groups.

	Group A ($N = 10$)	Group B ($N = 10$)	P value
Age (years)			
Mean ± SD	69.4 ± 8.28	64.2 ± 6.51	0.136
Range	57–87	55–74	
Sex			
Male	9 (90)	8 (80)	>0.999
Female	1 (10)	2 (20)	

Data are presented as frequency (%) unless otherwise mentioned.

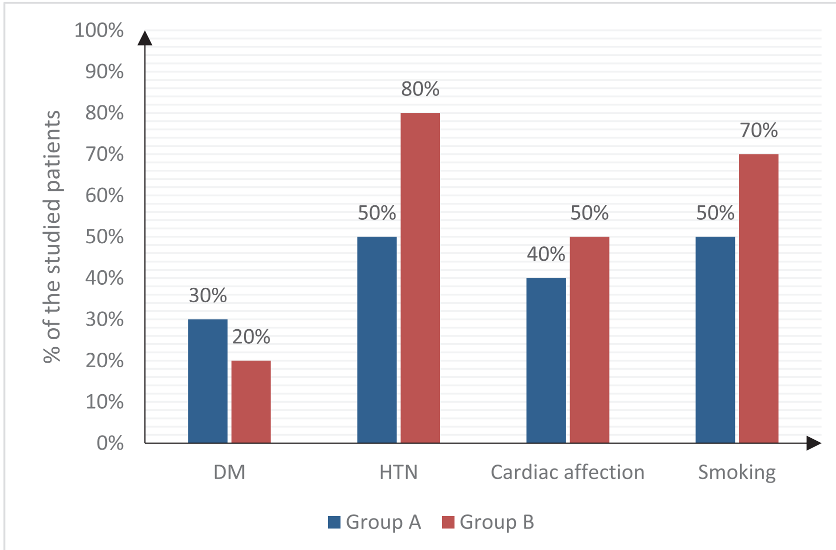

Fig. 1. Vascular risk factors of the studied groups.

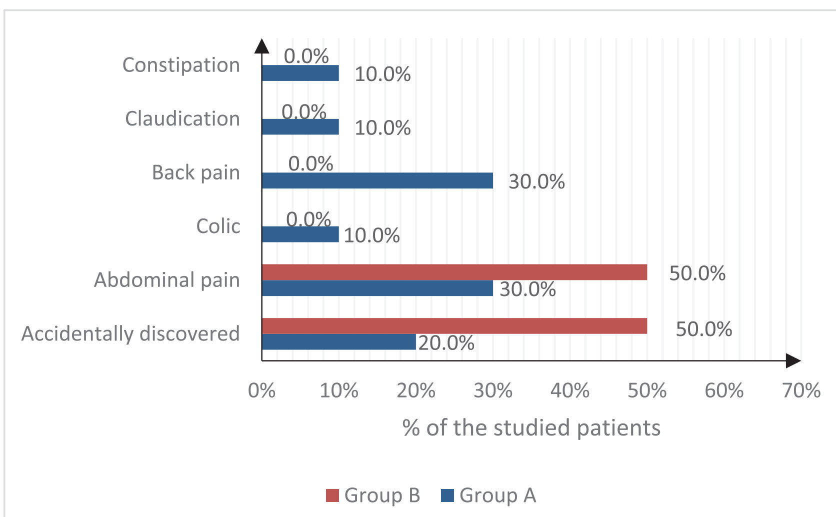

Fig. 2. Complaints of the studied groups.

($P = 0.003$). Regarding technical success, it was achieved in all patients in both groups.

Table 4 showed that there was no statistically substantial variation between the studied groups regarding periprocedural complications (only one patient treated by EVAR with IACA experienced groin hematoma), 30-day mortality (in two patients treated by EVAR with IVUS), sustained clinical improvement and CTA results (all cases in both groups were clinically improved with normal CTA except one treated by EVAR with IACA suffered from late-type 1b endoleak after 12 months) (Fig. 4).

Based on ROC curve analysis, access artery diameter (right or left iliac) by IVUS can significantly predict the effect of EVAR in decreasing aneurysmal size (AUC = 0.88, $P = 0.003$). At cut-off more than 14 mm, access artery diameter gives a sensitivity of 100 %, specificity of 80 %, positive predictive value of 83.3 %, and negative predictive value of 100 %.

Table 5 showed that there was no statistically substantial variation between CT and IVUS regarding aortic measures in patients with chronic kidney disease (Figs. 5 and 6).

Bland−Altman analysis shows that there was a reasonable degree of agreement between CT and IVUS in the evaluation of different aortic measurements with a mean bias of [−0.07 ± 0.61, LLOA (95 % confidence interval, CI): −1.26 (−2.03 to −0.491),

Table 2. Aortic measurements of the studied groups.

	Group A ($N = 10$)	Group B ($N = 10$)	P value
Diameter (cm)	7.5 ± 1.49 5.5−9.5	7.1 ± 1.26 5.5−9	0.61
Aortic neck length (mm)	23.8 ± 6.37 15−34	27.3 ± 5.1 20−35	0.192
Aortic neck angulation (deg.)	33.7 ± 12.25 15−58	33 ± 12.01 20−50	0.899
Aortic bifurcation diameter (mm)	27.3 ± 4.88 18−32	29.2 ± 8.79 19−42	0.558
Aortic neck diameter (mm)	24.8 ± 4.26 19−32	27.8 ± 3.08 24−32	0.088
Access artery diameter (iliac) (mm)	11.7 ± 2.31 10−17	15.2 ± 2.49 12−19	0.004*

Data are shown as mean ± SD and range.
*Statistically significant as P value less than 0.05.

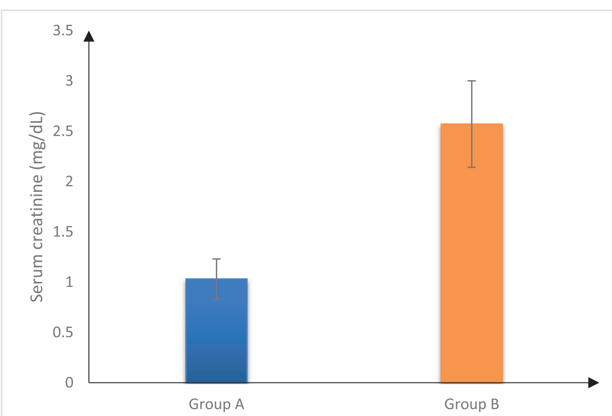

Fig. 3. Serum creatinine level of the studied groups.

Table 3. Procedural data of the examined groups.

	Group A ($N = 10$)	Group B ($N = 10$)	P value
Duration of procedure (h)			
Mean ± SD	2.5 ± 0.41	3.1 ± 0.28	0.003*
Range	2−3	2.5−3.5	
Technical success			
Yes	10 (100)	10 (100)	−
No	0	0	
Clinical success			
Decrease in size	2 (20)	5 (50)	0.364
Relief of symptoms	6 (60)	4 (40)	
Relief of symptoms and control of leak	2 (20)	1 (10)	

Data are presented as frequency (%).
*Statistically significant as P value less than 0.05.

Table 4. Outcome of endovascular repair of aortic aneurysms techniques of infrarenal abdominal aortic aneurysm in the studied patients.

	Group A ($N = 10$)	Group B ($N = 10$)	P value
Periprocedural complications			
No complications	9 (90)	10 (100)	>0.999
Groin hematoma	1 (10)	0	
30 days mortality			
No	10 (100)	8 (80)	>0.999
Yes	0	2 (20)	
Sustained clinical improvement			
Improved	9 (90)	10 (100)	>0.999
Late-type 1b endoleak after 12 months	1 (10)	0	
CTA			
Normal	9 (90)	10 (100)	>0.999
Endoleak with aneurysmal common iliac after 12 months	1 (10)	0	

Data are showed as frequency (%).

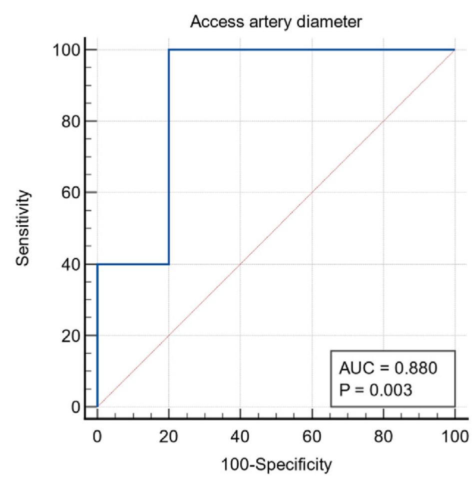

Fig. 4. ROC curve analysis of access artery diameter by IVUS in predicting the decrease in aneurysmal size. IVUS, intravascular ultrasound; ROC, receiver operating characteristic.

ULOA (95 % CI): 1.12 (0.351−1.89) for aortic diameter], [−0.9 ± 2.28, LLOA (95 % CI): −5.37 (−8.265 to −2.483), ULOA (95 % CI): 3.57 (0.683−6.465) for aortic neck length], [1.1 ± 6.52, LLOA (95 % CI): −11.68 (−19.945 to −3.423), ULOA (95 % CI): 13.88 (5.623−22.145) for aortic bifurcation diameter], [0.9 ± 3.07, LLOA (95 % CI): −5.12 (−9.01 to −1.23), ULOA (95 % CI): 6.92 (3.03−10.81) for aortic neck diameter], [0.9 ± 3.25, LLOA (95 % CI): −5.47 (−9.577 to −1.352), ULOA (95 % CI): 7.26 (3.152−11.377) for access artery diameter]. Based on our analysis, we concluded that IVUS is a valuable tool in assessing the aortic measurements accurately when compared to CT, therefore, in the repair of AAAs.

Table 5. Comparison between computed tomography and intravascular ultrasound regarding aortic measures of the same group of patients (N = 10).

	CT	IVUS	*P* value
Diameter (cm)	7.1 ± 1.16 6–9.5	7.1 ± 1.26 5.5–9	0.899
Aortic neck length (mm)	26.4 ± 4.14 19–35	27.3 ± 5.1 20–35	0.67
Aortic bifurcation diameter (mm)	30.3 ± 8 21–40	29.2 ± 8.79 19–42	0.773
Aortic neck diameter (mm)	28.7 ± 3.16 24–32	27.8 ± 3.08 24–32	0.528
Access artery diameter (iliac) (mm)	16.1 ± 2.08 12–19	15.2 ± 2.49 12–19	0.391

Data are showed as mean ± SD and range.
CT, computed tomography; IVUS, intravascular ultrasound.

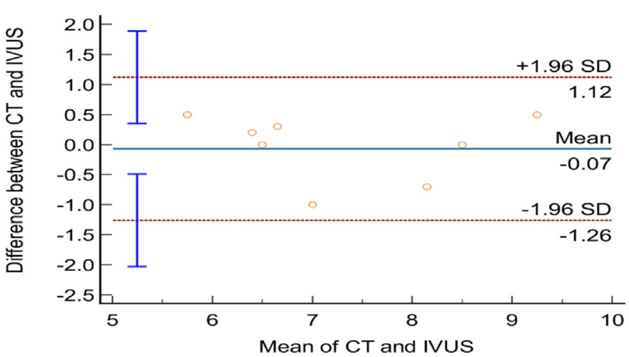

Fig. 5. Bland–Altman plot for the agreement between CT and IVUS in terms of aortic diameter. CT, computed tomography; IVUS, intravascular ultrasound.

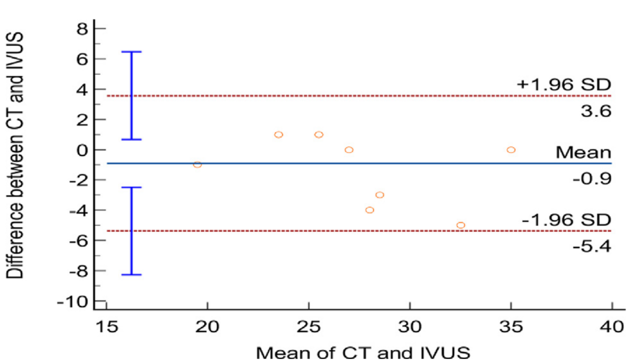

Fig. 6. Bland–Altman plot for the agreement between CT and IVUS in terms of aortic neck length. CT, computed tomography; IVUS, intravascular ultrasound.

4. Discussion

In this study, we demonstrated that by comparing both groups regarding aortic measurements, access artery diameter (right or left iliac) was substantially greater in group B (managed by EVAR with IVUS) as compared with group A (managed by EVAR with IACA) (P = 0.003). Tsujimura et al.[13] found that implanted stents were longer and smaller in diameter in individuals who had IVUS treatment. Fernandez et al.[14] reported that Their IVUS readings caused a modification in the size of the stent graft that had been originally selected based on an initial CT measure in 54 % of instances.

Jánosi et al.[15] found that in comparison to IVUS, CT showed considerably larger infrarenal aortic aneurysm diameters and somewhat larger mean diameters in the abdominal aorta. In this thesis, we illustrated that serum creatinine level was substantially different between the studied groups being higher in patients treated by EVAR with IVUS as compared to those treated by EVAR with IACA ($P < 0.001$). Hoshina et al.[5] found that in the IVUS group, renal malfunctions were more often comorbid, which suggests that patients in this group were more likely to need surgery.

Burlacu et al.[16] found that even in complicated atherosclerotic lesions, IVUS-guided treatments in patients with CKD seem to be as effective as the standard method and safe (both in cardiac and renal outcomes, without renal side events and greater kidney preservation).

In this study, we illustrated that there was no statistically substantial variation between the studied groups regarding periprocedural complications (only one patient treated by EVAR with IACA experienced groin hematoma), 30-day mortality (in two patients treated by EVAR with IVUS), sustained clinical improvement and CTA results (all cases in both groups were clinically improved with normal CTA except one treated by EVAR with IACA suffered from late-type 1b endoleak after 12 months).

Von Segesser et al.[17] found that in terms of conversion to open surgery, hospital mortality, and the results of endovascular aortic aneurysm repair utilizing either preoperative angiography or IVUS, it can be claimed that there is no substantial variation between the two groups evaluated. Early endoleaks seem to be less common with IVUS (6.1 %) angiography (25.8 %: $P5 = 0.05$).

The fact that the design of the endovascular stent graft has improved may have had an impact on these findings, although this study was not randomized. Bredahl et al.[18] found that in a sample of 278 individuals, the McNemar's χ^2 test found that IVUS and CTA were not diagnostically similar ($P = 0.002$), in contrast to IVUS and CTA ($P = 0.827$). The sensitivity of endoleak identification increased when IVUS was used *in lieu* of DUS, going from

45.6 % (95 % CI: 33.5−58.1 %) to 85.3 % (95 % CI: 74.6−92.7 %) ($P < 0.001$).

Tsujimura et al.[13] found that patients using IVUS or not did not substantially vary in their 12-month restenosis risk [10.2 % (6.9−14.9 %) vs. 10.3 % (5.4−18.6 %), $P = 0.99$]. In this study, we cleared that based on ROC curve analysis, access artery diameter (right or left iliac) by IVUS can significantly predict the effect of EVAR in decreasing aneurysmal size (AUC = 0.88, $P = 0.003$). At cut-off more than 14 mm, access artery diameter gives a sensitivity of 100 %, specificity of 80 %, positive predictive value of 83.3 %, and negative predictive value of 100 %. Vogt et al.[19] found that IVUS's predictive value, sensitivity, specificity, and kappa value were all greater than those of arteriography in these categories. According to a logit regression study, IVUS exhibited a high predictive value ($P = 0.0003$) for identifying aneurysmal sizes that were considerably shrinking as measured by duplex scanning.

In the present study, we found that there was a reasonable degree of agreement between CT and IVUS in the evaluation of different aortic measurements with a mean bias of [−0.07 ± 0.61, LLOA (95 % CI): −1.26 (−2.03 to −0.491), ULOA (95 % CI): 1.12 (0.351−1.89) for aortic diameter], [−0.9 ± 2.28, LLOA (95 % CI): −5.37 (−8.265 to −2.483), ULOA (95 % CI): 3.57 (0.683−6.465) for aortic neck length], [1.1 ± 6.52, LLOA (95 % CI): −11.68 (−19.945 to −3.423), ULOA (95 % CI): 13.88 (5.623−22.145) for aortic bifurcation diameter], [0.9 ± 3.07, LLOA (95 % CI): −5.12 (−9.01 to −1.23), ULOA (95 % CI): 6.92 (3.03−10.81) for aortic neck diameter], [0.9 ± 3.25, LLOA (95 % CI): −5.47 (−9.577 to −1.352), ULOA (95 % CI): 7.26 (3.152−11.377) for access artery diameter].

Blasco et al.[20] found that the average diameters were as follows: CT mean, 28.3 (9.8) mm; IVUS, 27.9 (9.7) mm; CT mean, 27.4 (9.2) mm. Good ($r = 0.98$; $P < 0.001$) correlation between the techniques was observed. The absolute values had a mean difference of 1.33 (1.3) mm. Systematic error was 0.59 (1.78) mm between CT minimum and IVUS ($P = 0.077$).

Beeman et al.[21] also believe that in order to accurately diagnose patency issues as well as other issues like kinking and stenosis, vascular US is more reliable than CTA. The relatively small sample size and the fact that the research was conducted at a single site are two of the study's shortcomings. Therefore, more research with a bigger sample size is required to confirm our findings.

4.1. Conclusion

Based on our analysis, we concluded that IVUS is a valuable tool in assessing the aortic measurements accurately when compared to CT, therefore, in repairing AAAs.

Conflicts of interest

There are no conflicts of interest.

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